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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/617,178 07/17/00 EFSTATHIOU S 5673-55696

HM12/0125
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EXAMINER

SPIEGLER, A

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

01/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/617,178

Applicant(s)

EFSTATHIOU ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE $\frac{1}{2}$ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to pharmaceutical compositions and kits, comprising a M3 protein encoded by a virus, classified in class 424, subclass 1.17 and 1.41.
 - II. Claims 11-13, drawn to a polynucleotide encoding a polypeptide, classified in class 536, subclass 23.4.
 - III. Claim 14, drawn to a method of treatment to produce an anti-inflammatory effect, comprising administering a pharmaceutical composition comprising M3 protein encoded by a virus, classified in class 435, subclass 5.
 - IV. Claim 15, drawn to a method of treatment to reduce or block entry of a virus into cells, comprising administering a pharmaceutical composition comprising M3 protein encoded by a virus, classified in class 435, subclass 5.
 - V. Claim 16, drawn to a method of detecting a chemokine, comprising contacting the chemokine with a reagent comprising an M3 protein, classified in class 536, subclass 24.31.
2. The inventions are distinct, each from the other because of the following reasons:
 - A) Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as

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distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

D) Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product in Group I can be used in other treatments, such as treatment to reduce or block entry of a virus or parasite, shown in Group IV.

E) Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product in Group I can be used in other treatments, such as treatment to produce an anti-inflammatory effect, shown in Group III.

F) Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product in Group I can be used in various treatments, such as the treatments shown in Groups III-IV.

G) Inventions III/IV/V are separate and distinct because the inventions require different ingredients, process steps, and endpoints. Groups III/IV/V are different methods requiring

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different method steps, wherein each is not required, one for another. For example, Group III requires search and consideration of producing an anti-inflammatory effect, which is not required by the other inventions. Group IV, requires search and consideration for reducing or blocking entry of a virus or parasite into cells of a subject, which is not required by the other inventions. Group V, requires search and consideration of detecting a substance that comprises a chemokine, which is not required by the other inventions.

H) Inventions II and (III-V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP 806.04, MPEP 808.01). In the instant case, the different inventions are not required one for another in that the DNA of Group II is not required for the methods of Groups (III-V).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. A telephone call was made to Susan Segal on January 18, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
January 24, 2001

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1660/600

1/24/01
Kenneth R. Horlick, Ph.D.